UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,103	11/12/2003	Douglas Craig Scott	9118M2	5133

27752 7590 08/06/2009

THE PROCTER & GAMBLE COMPANY
Global Legal Department - IP
Sycamore Building - 4th Floor
299 East Sixth Street
CINCINNATI, OH 45202

EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
08/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/706,103	SCOTT ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 8-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 8-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/26/09 has been entered.

2. Applicant's arguments filed 12/16/08 have been fully considered but they are not deemed to be persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-4 and 8-17 are pending in this office action.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating diseases (such as gingivitis, breath malodor, dental erosion or plaque, does not reasonably provide enablement for preventing the above diseases in a patient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2nd 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

The nature of the invention. The invention discloses using a composition comprising 35-65% of water insoluble particulate retentive agent further comprising an oral care active, a surfactant and a buffer for the prevention of conditions of the oral cavity.

The Predictability or Lack Thereof in the Art. Prevention is not practical with oral diseases due to the unpredictability of the condition. According to the American Dental Association (http://www.ada.org/public/topics/bad_breath.asp), bad breath can be caused by food, dry mouth etc, other oral diseases can be caused by health problems (such as diabetes) or lack of getting the oral cavity professionally cleaned. Some agents used to treat diseases of the oral cavity, such as bad breath, only mask the odor. The food that caused the bad breath must leave the system before bad breath can be stopped. Periodontal disease begins with plaque that is not removed during daily cleaning. When plaque is not removed it turns into calculus. It is impossible to remove all calculus with daily brushing (http://www.perio.org/consumer/faq_general.htm, pages 1-4). Therefore it is likely a small amount of gingivitis is present in between dental visits. In the case of the instant invention, the disclosed oral cavity diseases can be caused by different factors. Thus it is nearly impossible to protect against all diseases of the oral cavity with the claimed composition and given the highly unpredictable state of the art, the specification does not provide sufficient guidance or direction as to how to make and use the full scope of the presently claimed invention without requiring an undue amount of experimentation.

The Amount of Direction or Guidance Present. The disclosure teaches the composition can be used to stop the oral disease from becoming more serious but lacks any type of guidance that would lead one to believe that prevention is possible. This guidance or lack thereof is not commensurate with the full scope of the claims.

The Presence or Absence of Working Examples. The examples present in the specification are a representation of the effect of the drug when introduced to bacteria. There is a lack of examples showing the effect of the composition on a patient prone to the recited diseases.

The Breadth of the claims. The claim is broad because they read on "preventing".

Suggested language. Since the term "treatment" is a broad term, it will inherently cover therapies in which some protective function may also be present. Accordingly, the examiner recommends simply reciting method for "treatment" of periodontal diseases.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8 and 10-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kiyoshige et al. (US 4,689,221).

Kiyoshige teaches an oral dentifrice composition which prevents periodontal disease comprising from 15%-60% of magnesium carbonate or titanium dioxide (i.e., water insoluble, particulate retentive agent), an oral active (selected from fluoride compounds, vitamins, an antibacterial agent (i.e., cetylpyridinium chloride)), a surfactant and a buffer (i.e., phosphate buffer), (see col. 3, lines1-5, 20-21; 60-61; col. 4, lines 5-

15 and 40-41 as it relates to claims 1-2, 3 and 8 and). Kiyoshige does not teach the oral composition is effervescent; therefore it is reasonable to conclude that Kiyoshige is a non-effervescent composition (i.e., as it relates to claim 1).

With regards to the limitation of claims 1-2, 15 and 17 wherein the retentive agent having a water solubility of 1g/30 g at 25˚C, this is regarded as an inherent property of the compound, because products of identical chemical composition can not have mutually exclusive properties (see MPEP 2112.01).

Kiyoshige also teaches the composition is chewable (i.e., chewing gum, chewing gums are compressed tablet form) as required by instant claim 1 (see col. 3, lines 1-5, as required by instant claim 10). It is therefore reasonable that when such a composition comprises the same retentive agent (titanium dioxide or magnesium carbonate) with an oral active agent (fluoride ions), a buffering agent and a surfactant the chewed composition will be retained on the teeth and will be visible on at least 3-5 molar surfaces (as required by instant claims 1, 12 and 16).

As to the limitation “wherein the composition is a chewable dentifrice solid unit dosage form, is non- effervescent, non-cariogenic; and wherein the composition is visible on 2 to 3 molar or premolar surfaces to greater than 7 molar or premolar surfaces for 5 minutes to 60 minutes after a human subject chews two tablets of the composition for 5 to 30 seconds, brushes his or her teeth for 30 seconds, expectorates the slurry created from the brushing, and then rinses with 10 ml of water and expectorates again" (as required by instant claim 16), the intended use of a composition is given no patentable weight. “A preamble is generally not accorded any patentable

weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone". See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951)

Therefore it is anticipated that the composition being chewed comprising magnesium will deposit on some of the tooth surfaces (as required by instant claims 1, 12 and 16). Intrinsically once the composition of Kiyoshige is chewed, the oral cavity saliva is automatically buffered (as required by instant claim 13). Buffering is an inherent expected property, since the pH of the saliva reasonably is expected to change from 7-12 when an agent of a basic nature is placed in the oral cavity. Also the composition when chewed is bound to retain in the pits of the occlusal surface of one or more tooth surfaces (as required by instant claim 16). Providing sustained delivery of an oral care active for 5 minutes in the oral cavity of a subject for treatment of diseases or conditions of the oral cavity is therefore an inherent property of Kiyoshige's composition because the composition comprises all the required agents recited by the claims for providing the benefit of treatment of the oral cavity (as required by instant claim 14).

With regards to claim 12, the printed matter on a label or package insert of a kit or container does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert of a kit and the product, composition, or article of manufacture of

a kit or container. See *In re Haller* 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of *In re Haller*, it is stated that: "whether the statement of intended use appears merely in the claim or in label on the product is immaterial so far as the question of patentability is concerned . . . In accordance with the patent statutes, an article or composition of matter, in order to be patentable, must not only be useful and involve invention, but must also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new".

Moreover, the claimed articles of the kit remain fully functional absent the labeling or printed instructions for use.

Nevertheless, in the instant case, the kit claims are drawn to an old article or composition, which further comprises labeling instructions. The intended use, which is recited on the label or package of the insert, lacks a function relationship because the insert or label does not physically or chemically affect the chemical nature within the article of manufacture, and furthermore, the old article or old composition of the kit can still be used by the skilled artisan for other purposes. Therefore the old article or composition which are comprised with the claimed kit are unpatentable over the prior art, because they function equally effectively with or without the labeling, and

accordingly no functional relationship exists between the instructions for use and the composition.

Thus this claim is addressed as being drawn to an article of manufacture comprising an old composition of a kit and a package insert, the instructions on the insert bearing no patentable weight with regard to double patenting, 102 and 103 rejections.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 8-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiyoshige et al. (US 4,689,221) and Lawlor (US 6,706,256).

Kiyoshige et al. is applied here as above.

However Kiyoshige fails to teach the fluoride ion source provides from 200-300-ppm of fluoride ion.

Lawlor teaches a water insoluble particulate retentive agents, such as mica and zinc oxide (i.e., same as applicant's, see rational above; see col. 19, lines 22-40), an oral care active, (see abstract), a surfactant (see col. 18, lines 41-65), a buffer (see col. 22, lines 1-15) in the form of a chewing gum, a chewable solid unit, (see col. 15, lines 21-65 as required by instant claims 1, 10, 12 and 16). Lawlor also teaches the composition maybe used with brushing (see col.24, lines 45-48, as it relates to claim 1).

Because, Lawlor teaches mica and zinc oxide (i.e., identical compounds to the claimed invention), they intrinsically would have the same solubility of lg/30g at 250 C or less than lg/100g at 25˚C and therefore the limitation of claims 1- 2, 12 and 15-17 are met. One of ordinary skill in the art would also expect the composition when chewed will be visible on 4-5 molar for 5-60 minutes because the same agents used in Lawlor is the same recited in the claim 1 and specifically Lawlor teaches that the crunchy sensation

remains consumer noticeable (see col. 17, lines 25- 31as required by instant claims 1, 3-5, 12 and 16).

Further Lawlor teaches that the oral actives are selected from the group of anti-calculus agents, H2 antagonist etc, wherein the active agent the fluoride ion source provides from 100 ppm -1000 ppm (i.e., within the claim limitation of 9, see abstract and col. 11, lines 60-63, as required by instant claims 8-9). Lawlor also teaches the buffer is trisodium phosphate, (see col. 22, lines 1-15, as required by instant claim 11) and the composition is a compressed tablet (see col. 15, lines 30-31 as required by instant claim 10). Lawlor teaches the chewable dentifrices may be non-cariogenic (see col. 20, lines 43-55 as required by instant claim 1).

However Lawlor fails to teach the percentage of the retentive particulate is 35-65%.

Even though Kiyoshige fails to teach the concentration of the fluoride ion in the instant composition and Lawlor fails to teach the required percentage of the retentive particulate one of ordinary skill in the art would have been motivated to combine the teachings of Kiyoshige with Lawlor by modifying the teachings of Kiyoshige by adding to this composition a fluoride ion that will provide 200-300 ppm because fluoride ions are required for healthier teeth.

8. Claims 1-4 and 8-17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lawlor (US 6,706,256) in view of Fine et al. (US 4,374,822) for the

reasons made of record in Paper No. 20080710. Please note that claims 13 and 15-17 are include as the arguments are the same.

Applicant argues that Lawlor does not disclose any of the claimed retentive agents at the levels used in the present invention. That the composition of the present invention, when chewed, is deposited and retained in the subject's teeth for at least 5 minutes and up to 60 minutes .

Applicants further argues that the citing of the Fine reference does not close the loop and render the present invention obvious. While Fine discloses compositions containing broad ranges of water-insoluble polishing agents, it is clear that Fine's focus is its flavoring, and that it never even contemplated nor desired a composition that would stick.

In response a composition is a composition whether Applicant's goal was for the composition to stick to the teeth or not because intended uses are given no patentable weight. Lawlor specifically teach water insoluble particulate retentive agent such as mica, zinc oxide, and (see col. 19, lines 22-40). Therefore the argument that Lawlor does not teach any of the claimed retentive agents is found not persuasive because mica and zinc oxide would have the same solubility of 1g/30g at 25◦ C or less than 1g/100g at 25◦C as claimed. Next, Lawlor teaches the resultant crunchy sensation is noticeable. For example if a more concentrated form of the retentive agent are used in the composition the visibility of the composition will be adhere to the teeth longer.

Because Lawlor failed to teach the percentage of the retentive particulate as 35-65% and is silent to the teaching of a non-effervescent, Fine was introduced. Fine et al.

teach dental oral composition such as chewable tablet, the water-insoluble polishing agent such as (magnesium carbonate) which is one of the claimed retentive particulate that may be present from 20-75%. See col. 3, lines 26-36.

Thus one of ordinary skill in the art would have been motivated to combine the teachings of both Lawlor and Fine to achieve the claimed invention at the time the claimed invention was made, and for the reasons previously made of record.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
7/17/09

/Robert C. Hayes/
Primary Examiner, Art Unit 1649